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Regulatory Analysis Assessment for Proposed Rulemaking on OTC External Analgesics

INTRODUCTION

The Food and Drug Administration, in compliance with Executive Order 12044 on Improving Government Regulations, and in accordance with interim HEW guidelines, has assessed the economic impact of this proposed rulemaking (or existing regulation). Based on this assessment, it has been determined that a Regulatory Analysis, described in Executive Order 12044, is not required. The assessment supporting this determination follows.

ASSESSMENT

Under Executive Order 12004, a Regulatory Analysis is required if either one of the following two criteria are met:

1. The regulation (proposed or existing) causes an increase in total cost or price of goods or services to the national economy of $100 million within any one of the first five years of implementation.

2. The regulation causes increases in the cost or price of goods or services of 10 percent within any one year of the first five years of implementation in any industry or market, level of government, or geographic region; provided that this increase in cost or price of goods or services so affected exceeds $10 million annually.

Neither of these criteria were met as a result of the impact of this regulation for the reasons discussed below.

The annual retail sales for External Analgesic products is estimated to be approximately $150 million.

The proposed regulation will increase industry costs by only a small amount. Although relabeling and reformulation will be required for most products now marketed, the existing stocks of products, labels, and package inserts can be used since one year is allowed to implement the changes for compliance with the final OTC monograph.

No new equipment or personnel will be needed to effect the changes required in the OTC final monograph.

78N-0301

RA 1

Statement of Exemption and Environmental Assessment Report

for the Establishment of a

Proposed Monograph for OTC External Analgesic Drug Products

DATE:

ADDRESS: Division of OTC Drug Evaluation (HFD-510)
Food and Drug Admininstration
Department of Health, Education, and Welfare,
5600 Fishers Lane, Rockville, MD 20857.

STATEMENT: The Bureau has determined that this action is exempt from the requirement of preparing an Environmental Impact Analysis Report (EIAR). The exemption of this proposed action is specified in subparagraph (4) of paragraph (f)(21 CFR 25.1(f)). This statement conforms to the requirement established in paragraph (g)(21 CFR 25.1(g)).

REPORT: The Bureau has assessed the statement of exemption for this action and has concluded that it has been correctly applied in accordance with environmental regulations. This monograph specifies the conditions under which products already in commercial distribution may continue to be marketed. The Commissioner does not anticipate that the promulgation of this monograph will significantly affect the quality of the human environment.

William E. Gilbertson, Pharm.D.
Director
Division of OTC Drug Evaluation

ROUTING AND TRANSMITTAL SLIP Date 12-11-79

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REMARKS

re: Docket No. 78N-0301

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